EXHIBIT D

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 1629
THIS DOCUMENT RELATES TO:	Master File No. 04-10981
ALL PRODUCT LIABILITY CASES	Hon. Patti B. Saris Magistrate Leo T. Sorokin

DECLARATION OF KEITH ALTMAN

I, Keith Altman declare and state as follows:

1. My name is Keith Altman. I am employed by the law firm of Finkelstein and Partners and serve as the Director of Adverse Event Analysis for the firm. My address and contact information is as follows:

   Keith Altman
   Director of Adverse Event Analysis
   Finkelstein & Partners
   436 Robinson Avenue
   Newburgh, NY 12550
   800-634-1212 x 9263
   kaltman@lawampmmt.com

2. A true and correct copy of my c.v. is attached as exhibit Altman-A.

3. I have been working with computers and computer data since age 13. At 13, I spent one year working with teacher Herbert Cohen on numerical simulations. I attended the State University of New York at Stony Brook as an undergraduate with a double major in Physics and Astronomy. While there, I held several paid and unpaid positions concerning software development and data analysis. For example, I was a paid employee of the Research Foundation of the State University of New York. In that capacity, I developed the data analysis software as well as control software for a particle accelerator in a quantum electronics lab. I also worked on computations associated with Supernova 1987A, infrared telemetry data, and developed a data model for the error analysis calculation associated with the distance to the Hyades Cluster. These and other similar projects contributed to my preparation to work with data and computers and I employ these skills and practices to this day.

4. As a fundamental part of my education, computers and data played an integral role. Aside from my research activities, I used computers extensively throughout my education.

5. In my professional capacity, I have been analyzing computer data for the last 19 years. I have been responsible for the preparation and computational support of thousands of data sets in that time. I am routinely engaged to perform computations on these data sets to support individuals in a wide variety of disciplines. Regardless of the content of the data, the principles associated with data computations are generally invariant and, therefore, I am able to work with computer data in areas I have never worked on before.

6. I have been working with pharmaceutical adverse event data since 1998. Adverse event data is data associated with untoward effects of pharmaceutical products. I have possession of the entire publicly-available adverse event data from the FDA dating from 1969. To date, that represents more than three million adverse event reports. I have prepared those data into a database from which I routinely provide customized data compilations.

7. In my professional capacity I have provided assistance to the FDA with respect to its handling of data. For example, in mid 2003 I detected a flaw in the data provided by the FDA as part of its adverse event reporting extracts made available to the general public. This flaw, involving erroneous calculations of last best cases for reports by the FDA, would likely have led to serious errors in working with the data. I communicated my discovery to Paul Reinstein of the FDA, the individual responsible for the extract of the FDA AERS data. As a result of my discovery the FDA has abandoned the practice that affected the data and communicated this decision publicly to all users of the AERS data worldwide.

8. I have compiled analyses of adverse event data with the use of math and computers for approximately 50 different pharmaceutical products, including Diet Drugs, Lariam, Accutane, Meridia, Rezulin, Effexor, Paxil, Baycol, Hormone Therapy, Children's Advil, Viagra, Ortho Evra, and Neurontin. These analyses include studies of adverse events from each type of clinical study, including blind studies, double blind placebo studies, and uncontrolled studies in which the effect of a drug on a human is compared to the effect of the same drug within a larger group of humans. These analyses also include studies of clinical reports to the FDA submitted by a pharmaceutical company seeking approval for a new drug, known as a new drug application, and studies of such reports after a drug has received FDA approval. These analyses also include studies of individual case reports and adverse event reports which are required by law to be maintained by the FDA and by the pharmaceutical company whose drug or product is the subject of such reports.

9. The type of mathematical computations I perform as a part of my routine practice include counts of numbers of reports for various adverse event terms, calculations of percentages between drugs, comparisons of such percentages (Proportional Reporting Rate or PRR), and time trends of reporting.

10. I routinely do this type work outside of litigation and, in particular, in support of drug development projects which lead to application to the FDA for new drug approval on

behalf of pharmaceutical companies and on behalf of the experts who evaluate such drugs for the purpose of NDA submissions and label submissions to the FDA. Included in my non-litigation work I have performed the statutorily-mandated safety analysis for three new drug applications, two of which have been approved and the third of which is in the final stages of approval. Of the two approved I performed the safety analysis for one and performed the post marketing adverse event section, including the analysis, for the other. The FDA specifically reviewed my data computations in all these submissions and found no errors, nor did the FDA express any concerns of either my methods or the accuracy of the data I submitted.

11. I used the same methodology in preparing data for use by the experts in this case that I use in my drug development projects.

12. I am a member of the International Society of Pharmacoepidemiology and the Drug Information Association. In addition, I regularly review abstracts for the International Society of Pharmacoepidemiology (ISPE) annual scientific meeting. In 2007, I submitted three abstract proposals to the ISPE scientific committee regarding the work I do with the FDA adverse event data, specifically including my work on Proportional Reporting Rate analysis. All three abstracts were peer reviewed and were accepted for presentation at the conference. One of the abstracts was selected for one of only twelve oral presentations at the methods portion of the conference hosted by Ken Rothman, one of the preeminent epidemiologists in the world.

13. I am not assisting in this litigation in an expert witness capacity. However, I have been qualified as an expert witness in my field by a court on the topics of adverse event reporting, adverse event reporting systems, and pharmacovigilance. South Carolina v. Pittman (2005).

14. In addition, the work I do to provide summaries of clinical data, adverse event reports, and pharmacovigilance practices to testifying expert witnesses has been accepted as work on which expert witnesses in specific litigation may rely under Federal Rule of Evidence Rule 703. Furthermore, these charts are objective summaries of voluminous sets of data. All of my work is readily verifiable and I routinely provide all of the underlying data for review.

15. In addition to the publicly available adverse event data from the FDA, I am in possession of all of Pfizer's discovery in this case. I have spent extensive time working with Pfizer's internal adverse event database. I have employed the same methods to analyze Pfizer's database as with other adverse event databases and other databases in general and am confident that I am qualified to accurately report the contents of the database.

16. Neither Pfizer, Inc., in the motions and briefs filed herein, nor any witness in this case have stated that any computations performed by me in this case was incorrect in any way. No math error, nor any statistical error, nor any error in allocating the nature, type, frequency, or degree of any evidence of suicides or attempted suicides by any patient

taking Neurontin has been stated or even claimed by Pfizer or any witness in this case to have been found in my work.

17. All charts, tables of data, and allocations of patient type, (such as psychiatric, pain, and 'other' patients and the years, numbers, and frequency of suicide reports, suicide attempt reports, and reports of behavior associated with suicidality) were of the type which I routinely provide to the FDA and to expert witnesses who need such data and charts. I have not exercised any subjective judgment concerning the data. I checked them for accuracy before I provided them to Pfizer and to Dr. Blume and have checked them since. I found no errors in them.

18. The work I provided to Dr. Blume is of the type she routinely uses both in her practice in submitting new drug applications to the FDA and as an expert witness.

19. Prior to the deposition of plaintiffs' experts in this case, I personally prepared and submitted a computer data disk with all of the computational materials I had used and prepared for this litigation for adverse event compilations and objective summaries. The original source of the data was Pfizer's own records and the publicly available FDA data. I provided a copy of this data disk to the defendants in this case.

20. I was involved with a meet and confer with defense counsel to discuss the contents of the disk. Defense counsel had the opportunity to question me about the contents of the disk to their satisfaction. Using the disk I had provided to them, Pfizer and its counsel had the ability to verify the accuracy of any chart prepared for or by Dr. Blume if they chose to do so.

21. In early 2004, as part of the routine analysis of FDA adverse event data, the data showed a large increase in the number of completed suicide reports among Neurontin patients reported by Pfizer in the first half of 2003. Specifically, the data showed that between November 1997 through the end of 2002, Pfizer reported 8 completed suicide reports to the FDA. This yields 1.6 reports per year. The data also showed that in the *first* half of 2003, the company reported 17 reports of completed suicide to the FDA. This yields 34 reports per year and represents a 20 fold increase in the reporting rate of suicide.

22. These observations were the basis for my filing a citizen's petition with the FDA seeking to change the label and include a warning for completed suicide which was not in the label at that point in time. In this case, Pfizer has suggested that the source of the data in my citizen's petition was in some way influenced by notoriety associated with advertising performed by my firm, Finkelstein & Partners. This is not true.

23. Pfizer and its witness Dr. Weiss-Smith have misrepresented or misinterpreted the timing of these increases. Contrary to the representations by Defendants, these increases in Neurontin suicide reports were not as a result of publicity from the citizen's petition or from any advertising effort by Finkelstein & Partners. The source of the seventeen reports of completed suicide reported by Pfizer to the FDA, which took place in the first half of 2003, were poison control centers, not clients or potential clients who wanted to

sue Pfizer. Importantly, I did not join Finkelstein & Partners until the second half of 2003 and neither Finkelstein and Partners nor I began to review the subject of Neurontin litigation until after I joined the firm.

24. With respect to any notoriety bias, Dr. Blume has always requested that I confine analyses to data before the 3rd quarter of 2003 for signal detection purposes. She clearly recognized that such a bias was possible after that point in time and wanted to be sure that her opinions were not influenced by such data. On occasion, she would ask me to go beyond that point in time for the purpose of seeing the effect of the notoriety bias.

25. The following statements address mistakes, misrepresentations, or misleading statements made by Pfizer in the pending motions to exclude plaintiffs expert witnesses (hereafter the 'Daubert motion') or for summary judgment.

26. On page 39 of the Daubert motion brief the Defendants mis-state my involvement in the *Meridia* litigation. Contrary to their statements, I was not an expert witness in that case, and I had never been offered or disclosed as an expert witness in that case. Further, in the *Meridia* opinion cited by Defendants, the judge ruled that I had not been disclosed as an expert nor did I need to be an expert witness statistician to provide the basic computational analysis in that case. Defendants also state that the judge excluded my opinions in the *Meridia* case. That is not true; the opinions excluded were not mine and I do not agree with the expert's misuse of charts I created for the purposes of stand alone proof of causation.

27. Additionally, Defendants here claim that the *Meridia* Court ruled that Proportional Reporting Rate (PRR) analysis is unreliable for all purposes (Defendants' Daubert Motion at 40). The *Meridia* court ruled only that *standing alone*, PRR is insufficient to "speak directly to the issue of causation." Here, in the Neurontin litigation, I did not calculate PRR's for Dr. Blume to stand alone to establish that Neurontin is the cause of suicide or of attempted suicide nor, to my knowledge, has Dr. Blume expressed that opinion. Her opinion is and, to my personal knowledge has been, that the method for which a PRR is used is to evaluate whether there is *a signal of a safety problem* that, when combined with other information, supports the conclusion that Neurontin has the biological capacity to cause patients who take it to commit or attempt suicide.

28. Pfizer counsel also claim, Daubert motion page 41, that a chart I created demonstrates the absence of causation. This statement demonstrates that they do not understand the chart. Attached as Exhibit Altman-B is a copy of the chart.
    a. Defendants claim that the chart demonstrates that the reporting rate of suicide went down after the first quarter of 1994 which demonstrates a lack of a causal relationship.
    b. Warner – Lambert (Pfizer's predecessor in marketing Neurontin), received the first completed suicide report from post marketing in the fourth quarter of 1994.
    c. Before this time the cumulative percentage of suicide reports was 0; it is not normal methodology when graphing such data to graph a time period before there was an event.

d. After the first event, there were no suicides until 1997. Since the total number of reports was increasing during the same time period, the percentage *would* go down. The defendants use such data to claim that the chart shows there is no causal relationship.
e. However, this disregards that there were relatively few serious adverse event reports received by the company in the first few years of marketing. Therefore, isolated reports can have a large effect on the percentages. Such effects are routinely disregarded.

29. Pfizer, in its criticism of the chart, disregards that by the 4th quarter of 2002, covering the years when the off-label use of Neurontin is at its peaks, the percentage of serious adverse events had exploded.

30. Pfizer misrepresented to the court that this is because of notoriety bias from the public awareness of the citizens petition to the FDA or from the efforts of Finkelstein & Partners to bring the suicidality potential of Neurontin to the public's attention, but that is not true since the statistical increase came long before any involvement by Finkelstein and Partners (3rd Quarter 2003), and long before the observations I made led me to file the citizen's petition.

31. More importantly, and, mathematically, for the percentage to increase so much after the drug had been on the market for as long as it had means that the percentage of reports for the first half of 2003 were enormously different. After the completion of discovery in this case, it is now observed that in fact, there were approximately 782 serious adverse event reports in the period October 1, 2002 to June 30, 2003, including 22 completed suicides (some 3% of the serious adverse event reports in that period).

32. I attach several additional charts prepared by me at the direction of Dr. Blume. These charts are based upon the data I provided to defendants and which I extracted from the adverse event data provided by the defendants and the FDA database, themselves too voluminous and extensive to provide in their entirety. I prepared these charts using the same methodology as the work I do for new drug applications and for safety summaries as well as for work to be relied on by expert witnesses.

33. These charts are consistent with Dr. Blume's opinions expressed in her report and in her deposition. They represent objective numerical summaries of the contents of the databases. Dr. Blume may use them as demonstrative exhibits in the hearing or in any trial of this case.

34. To the best of my knowledge, no Pfizer employee nor any expert ever testified that the company had performed any computations or summaries concerning adverse events in off label populations for any off-label indication other than neuropatic pain.

35. The defendant companies have maintained that there was no signal for suicidal behavior at any time before the 3rd quarter of 2003.

36. However, within the company database of adverse events is data that identifies the indication (the medical condition of the patient) for which the drug was used. Under the direction of Dr. Blume, I prepared a chart that showed the percentage of suicidal and self injurious behavior reports against serious adverse event reports for various groups of Neurontin indications. This chart is attached as exhibit Altman-C to this affidavit. The chart demonstrates that there appears to be a large difference between psychiatric indications and other indications. According to standard statistical calculations, the results are statistically significant by 6/30/99.

37. I attended the defense expert deposition of Dr. Sheila Weiss-Smith in January of 2008. As part of her expert report on page 21, Dr. Smith-Weiss provided a chart suggesting that there was no signal for either suicide or suicide attempt until after 2004. Exhibit Altman-D. Her use of the chart was in error.
    a. Before November of 1997 there was no term in the FDA database for completed suicide. Any chart that contained a time period before 1997 would not contain any suicide for any drug or the background.
    b. If the number of reports of an event is 0, then the percentage of reports for that event is also 0.
    c. Dr. Weiss-Smith stated that she calculated the ratio as one percentage divided by the other. If the two percentages are 0, then one would divide 0/0. It is a mathematical fact that division by 0 is undefined. Therefore, 0/0 is undefined.
    d. Since 0/0 is undefined, any chart that shows such a ratio as any value other than undefined is factually wrong.
    e. Dr. Weiss-Smith's chart shows the ratio for suicide prior to 1998 as 0. Since the ratio is 0/0, her chart is factually wrong.
    f. The only mathematical interpretation of her chart is that prior to 1998 there were zero suicides in Neurontin while there was at least 1 suicide in the background of all other drugs. This is mathmatically impossible as shown above.
    g. Starting the completed suicide data in 1994 has the mathematical effect of causing differences to become visible later in time than they really occur. As an example, if there were 100 total reports for Neurontin before suicide was used as a term and then in the first year of use there were 10 suicide reports out of 20 total reports, by starting in 1994, the percentage is 10/120 or 16.7% against 10/20 or 50%.

38. At the direction of Doctor Blume, I created a correct version of the chart that Dr. Weiss-Smith attempted to create but used the following corrections.
    a. First, since the term for completed suicide did not even exist in the MedDRA lexicon before November 1997, the chart begins in the 4th quarter of 1997.
    b. Instead of using the single term 'completed suicide,' Dr. Blume instructed me to use the MedDRA term "suicidal and self injurious behavior;" that phrase includes completed suicide, suicide attempt, and suicidal ideation. This is a standard definition from the medical dictionary used by the FDA.
    c. Dr. Blume then instructed me to use serious reports only. There is a regulatory definition for serious events. Because some companies may request waivers to

not submit non-serious reports, it is standard methodology in calculating the statistics of adverse events and pharmacovigilance to exclude non-serious reports.

d. The reports were then limited to instances in which the reporter believed that there might be some relationship between the drug and the event.
e. Finally, as discussed above regarding the methodology used for composing PRR charts, the percentages of both the background and the drug were shown instead of the ratio.
f. For the time period in which there were no events, this corrects Dr. Weiss-Smith's chart in her report.

39. A review of the chart attached as exhibit Altman-D shows that there is a statistically significant difference between Neurontin and background starting in the 4th quarter of 1999. This result is consistent with the computational summary of the off-label indications discussed above.

40. At Dr. Blume's request, I reviewed the chart prepared by Pfizer employee Christopher Pacella attached as exhibit Altman-E. I was asked to prepare the information in a similar manner based upon the Pfizer internal database which was available to me. Furthermore, Dr. Blume asked that I limit the computation to serious reports and run the data using MedDRA high level terms. Attached as exhibit Altman-F is the results of this anlaysis.

41. To the best of my knowledge, all charts and computations created by me in this litigation are true and accurate summaries of voluminous materials produced by Pfizer in this litigation or publicly available from the FDA. I have exercised no subjective interpretation of any of the data and if desired, Pfizer has the ability to verify everything I have done.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 3rd day of April, 2008, in Massapequa Park, NY.

Keith Altman